

Application No. 09/902,016

Art Unit: 3627

REMARKS

Claims 1-32 stand pending in the application and claims 1-3 and 5-32 stand rejected in the final Office Action while claim 4 stands objected to.

Applicant herewith amends claims 4, 5, 7, 11-13, 15, and 16, cancels claims 1-3 and 17-32 and adds no new claims. Thus following entry of the amendments presented herewith claims 4-16 stand for examination on the merits. Applicant submits only minor amendments intended to place the pending claims in condition for allowance, and suggests that said amendments do not raise additional issues or require search of additional or other prior art.

Applicant respectfully requests entry and favorable consideration of the amendments and remarks presented herewith.

Claim Rejections Based on 35 U.S.C. §102

Claims 4 and 5 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,497,655 to Linberg et al. (Linberg).

Applicant herewith amends claim 4 to distinguish over Linberg since the claim, as amended, includes subject matter not found in Linberg. That is, Linberg does not include *each and every* claimed element and thus the rejection based solely upon Linberg should be withdrawn. For example and without limitation, Linberg fails to disclose or suggest a system for manufacturing an implantable medical device (IMD) which is central to the instantly claimed invention.

The "PPM" (prescriptive programming module) referred to in support of the rejection is wholly distinguishable from the structure and methods recited in the claims. In fact, the PPM is used to upgrade or alteration of an *existing and implanted* IMD. The following excerpt from Linberg should help make this point clear:

Referring to FIGS. 8A and 8B, the operation of PPM 104 is shown. As discussed hereinabove, PPM 104 relates to a remote programming of IMDs 10, 10' and 10" to install prescriptive functions. Specifically, the scheme relates, inter alia, to the remote installation of data that is in a

Application No. 09/902,016

Art Unit: 3627

repository as part of a recommended medical upgrade or alterations to IMDs 10, 10' and 10".

The PPM software is initiated by the physician under logic step 210. Subsequently under logic step 212 a secure mode is activated which includes encrypted operative to ensure security. The user is then authenticated under logic step 214. The secure mode triggers decision step 216 where the authenticity of the user is verified. If not verified the session is terminated under logic step 215. If the user is authenticated, access to an existing data repository is allowed under logic step 218. The menu includes an option to add new prescription data under decision block 220. If the session does not concern the addition of new prescription data, the logic proceeds to step 221 and the session is terminated. However, in the event a new prescription is to be added, the logic proceeds to install the required data under logic step 222. Thereafter, the accuracy of the data is confirmed under logic 224. The session for installing a new set of prescription data ends at logic step 226.

In the alternate, if the session concerns the review of patient data to ultimately install prescriptive data and/ or review the data to develop a new set of prescriptive data based on the performance history of IMDs 10, 10' and 10"; the menu provides the option to move to decision step 228. If that option is not selected, the session terminates at step 229. In the event the user elects to review the patient data and ultimately install a prescriptive program as needed, the logic proceeds to step 230 where the data is upgraded, altered or enhanced based on the patient history and other clinical parameters and decisions. The alterations and modifications are installed in the patient file under logic step 232. Thereafter, the physician will call the patient under logic step 232 to inform to the patient that a new program will be installed remotely. Consequently the new program is transferred via wireless communication systems, in the manner described hereinabove, under logic step 236. The transfer is then recorded under logic step 238 and the session terminates at logic step 240. (emphasis added.)

Claim Rejections Based on 35 U.S.C. §102

Claims 4 and 7-11 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 5,725,599 to Alt et al. (Alt).

Applicant herewith amends claim 4 to distinguish over Alt since the claim, as amended, includes subject matter not found in Alt. That is, Alt does not include *each and every* claimed element and thus the rejection based solely upon Alt should be withdrawn. For example and without limitation, Alt - like Linberg - merely deals with an upgrade or programming change *following*

Application No. 09/902,016

Art Unit: 3627

implantation of an IMD. The following excerpt (Title and part of the first line of the Abstract), makes this abundantly clear:

Programmably Upgradable Implantable Medical Device

Abstract

An implantable cardioverter/defibrillator device is implemented to be selectively non-invasively upgraded from time to time after implantation... (emphasis added.)

Since Alt fails to disclose methods and apparatus for manufacturing an IMD, Alt clearly cannot be used to support a rejection grounded in lack of novelty which should thus be withdrawn.

In support of the traversal of the rejections based on 35 U.S.C. §102, Applicant challenges the Examiner to locate the following claim limitation (from independent claim 4) in either Linberg or Alt:

a processing circuit coupled to the storage device to select components to be integrated in the initial manufacturing of the IMD based on the patient-specific data; (emphasis added.)

Assuming the recited claim limitation cannot be found in either Linberg or Alt, the rejections must be withdrawn as anticipation requires that *each and every claim limitation must be found in a single reference* (either expressly or under principles of inherency).

Claim Rejections Based on 35 U.S.C. §103

Claims 12-16 stand rejected as being unpatentable over Alt in view of U.S. Pat. No. 6,298,443 to Colligan et al. (Colligan).

With respect to Alt, Applicant reaffirms and incorporates by reference the remark previously made as if fully set forth herein. In sum, Applicant suggests that Alt cannot be used as a primary reference to construct the required *prima facie* obviousness rejection because it does not even contemplate custom manufacturing of IMDs. Thus, a person of skill in the art would not even review Alt if attempting to invent a custom manufacturing system for IMDs (which is one

Application No. 09/902,016

Art Unit: 3627

reason *Alt* is devoid of any disclosure regarding monitoring inventory levels and transferring customized order from a remote site to an inventory management system). Likewise, Colligan (assigned to the Dell computer manufacturing company) fails to disclose or contemplate custom manufacturing of IMDs - for perhaps obvious reasons. The Abstract of Colligan is very instructive regarding the fact that the invention merely relates to provision of a custom CD-ROM along with a pre-programmed computer system.

A method and system for supplying a software image to a computer system utilize a custom-programmed compact disk (CD) ROM that is configured for a specified individual computer system and constrained to be downloaded to and operable on only the specified individual computer system. The method and system further utilize an installation procedure for restoring the specified computer system to the software state that the computer was in at the time the computer left the factory after initial configuration and downloading. The custom-programmed CD ROM 106 is delivered to a customer in combination with a bootable flexible diskette 108, and an instructional technical instruction sheet for usage by the customer to restore the computer system to a "factory new" software condition.

The Examiner has failed to assert any basis for making the proposed combination of *Alt* and Colligan and Applicant can find no support for making the combination. However, assuming *arguendo* that the combination is reasonable, Applicant asserts that the claimed invention would not result. For these and the foregoing reasons, Applicant respectfully requests that the rejections posed in the final Office Action be withdrawn so the claimed invention can pass to timely issuance as U.S. Letters Patent.

CONCLUSION

Applicant herewith amends the dependent claims merely for convenience (especially the preambles thereof) and not for any reasons related to patentability. Applicant respectfully asserts that all presently pending claims 4-16 are now in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 13-2546.

Application No. 09/902,016

Art Unit: 3627

The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,

22 Feb. 06
Date

P. McDowall
Paul H. McDowall
Reg. No. 34,873
(763) 514-3351
Customer No. 27581